K080016

510(k) Summary of Safety and Effectiveness

FEB - 5 2008

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402)-537-5213

Date Prepared: January 02, 2008

Name of Device:
Trade Name: nRBC-Chex for ADVIA®
Common Name: Assayed Hematology Control
Classification Name: Nucleated Cell and Red Blood Cell Control (864.8625)

Predicate Device: nRBC-Chex for LH (K060083) Manufactured by Streck

Description:
nRBC-Chex for ADVIA® is stabilized suspension of human and animal blood, in a solution containing biological salts and anti-microbial preservatives. The product is packaged in plastic vials containing 4ml. The closures are polypropylene screw caps with polyethylene liners. There are two different levels. Level 1 has a low count and Level 2 has a higher count. The vials will be packaged in a two (2) or twelve (12) welled vacuum formed "clam-shell" container with the package insert / assay sheet. The product must be stored at 2 - 10°C.

Intended Use:
nRBC-Chex for ADVIA® is an assayed whole blood control designed to evaluate the accuracy and precision of the Siemens Healthcare Diagnostics Inc. hematology analyzers in the measurement of the nucleated red blood cell parameter. Refer to product assay sheet.

Comparison to Predicate Device:
nRBC-Chex for LH and nRBC-Chex for ADVIA® are both multi-parameter hematology control materials. They both contain RBC, WBC, and nRBC components. Unlike the 75 day closed vial stability of nRBC-Chex for LH, nRBC-Chex for ADVIA® meets the claim of a 45 day closed vial stability. nRBC-Chex for ADVIA® is designed to evaluate the accuracy and precision of Siemens Healthcare Diagnostics Inc. hematology analyzers listed on the products assay and nRBC-Chex for LH was designed for the Beckman Coulter® LH 750/LH 755.

Discussion of Tests and Test Results:
Four types of studies were conducted to establish performance of nRBC-Chex for ADVIA®. The four tests conducted were Closed Vial Stability, Open Vial Stability, Run to Run Reproducibility, and Site to Site recovery of values. All testing showed that nRBC-Chex for ADVIA® is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests:
nRBC-Chex for ADVIA® is an effective quality control material for evaluating the accuracy and precision of the Siemens Healthcare Diagnostics Inc. ADVIA® 2120 in its measurement of the nucleated red blood cell parameter. It meets the claim of a 45 day closed vial, and a 14 day open vial stability and consistent run-to-run performance. Reproducibility studies and Closed Vial Stability results confirm lot-to-lot consistency in the manufacture of nRBC-Chex for ADVIA®. Customers can be assured of a reliable quality control material that meets their expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 5 2008

Streck
C/O Erin Johnson
7002 South 109th Street
Omaha, Nebraska 68128

Re: k080016
Trade/Device Name: NRBC-Chex for Advia
Regulation Number: 21 CFR 864.8625
Regulation Name: Assayed Hematology Control
Regulatory Class: Class II
Product Code: GJR
Dated: January 2, 2008
Received: January 3, 2008

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: nRBC-Chex for ADVIA®

Indications For Use:

nRBC-Chex for ADVIA® is an assayed whole blood control designed to evaluate the accuracy and precision of the Siemens Healthcare Diagnostics Inc. hematology analyzers in the measurement of the nucleated red blood cell parameter. Refer to product assay sheet.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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